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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,709	09/07/2000	Annika Bjore	3525-96	6411

7590

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 03/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/623,709

Applicant(s)

BJORE ET AL.

Examiner

Mark L. Berch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- ✓1. What does “as appropriate” entail in e.g. claim 1. Appropriate to whom and for what?
- ✓2. What does “terminated” mean at e.g. page 67, line 10? Substituted is already covered earlier in the line, so what does “terminated” do? Likewise page 64, line 4.
- ✓3. “Derivative” at page 70, line 10 of what structure?
- ✓4. Claim 2 is improperly dependent on claim 1. The interruption by an oxygen atom is not provided for by claim 1. It also recites cycloalkyl, which does not appear in claim 1.
- ✓5. The claim 15 formulation is not a proper composition. A complete and proper composition claim must recite a carrier, otherwise it is just a compound claim.
- ✓6. The term, “for use” in claims 16-17 simply states an intention, which is a mental step, not a patentable limitation. Hence the claim is improperly dependent, as it does not further limit the claim on which it depends. Alternatively, this may be

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intended as a method of use claim, in which case, the claim is garbled, as it begins as a compound claim, and ends as a method claim.

- ✓7. "Use of" (claim 18-19) is not a permitted format for US patent claims (*In re Fong*, 129 USPQ 264).
 - ✓8. The phrase "or susceptible to" is not a proper limitation in claim 20. Everyone is susceptible to arrhythmia.
 - ✓9. Claims 22-25 are improperly dependent on claim 21. There is no provision for protected versions in claim 21.
 - ✓10. In claim 26, the various formulae such as XXVIII are not "defined herein". This is an independent claim.
11. Further, it is impossible to tell what is going on in claim 26 because the reagents don't seem to be related to the final products. For example, XXIX is converted how into XVII or VIII? How would option (1) produce any of these compounds?

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most aspects, does not reasonably provide enablement for step (d) for D = H, or step (e). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Reduction all the way to D=H will not work; it will cleave the carbamates at the other end of the molecule.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most aspects, does not reasonably provide enablement for step (d) for A = fourth choices. The specification does not enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The circumstances has an ester, as the starting material for the reduction, -O attached to the carbonyl which will be reduced. The claim then requires that the carbonyl be reduced without cleaving the other C-O i.e. C(O)OC reduced to CH₂OC, an ester to a non-cyclic ether. That is impossible; there is no such reduction.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most aspects, does not reasonably provide enablement for the scope of (r). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

How would e.g. the methyl be converted to the ethyl or to the nitro? How would alkoxy be converted to alkyl?

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

See point 11 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to

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which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, and 14-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alstermark.

The reference embraces the claimed compounds, although the prepared compounds of the reference are excluded by the first proviso. For example, there are many species where the side chain on the left is a benzyl group, i.e. where A = B = bond and D = H. However, the D = methyl compounds would be obvious. The reference teaches that R¹¹ can be alkyl, and indeed, that is given as one of the preferred choices at column 4, line 23. With regard to the intermediates II, IV, VIII, XVII claimed in claims 22-25, the same intermediates appear with the same labels in the reference, and the same processes are present.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10, and 14-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6291475. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because of reasons set forth above. The same issues apply.

Claims 1-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 09/623705. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no patentable distinction between the two cases. 09/623705 differs because it has an extra methyl group attached any one of several locations.

Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. As was stated in *In re Grose*, 201 USPQ 57, 63, "The known structural relationship between adjacent homologues, for example, supplies a chemical theory upon which a *prima facie* case of obviousness of a compound may rest." The homologue is expected to be preparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood*, 199 USPQ 137; *In re Hoke*, 195 USPQ 148; *In re Lohr*, 137 USPQ 548; *In re Magerlein*, 202 USPQ 473; *In re Wiechert*, 152 USPQ 249; *Ex parte Henkel*, 130 USPQ 474; *Ex Parte Fischer* 96 USPQ 345; *In re Fauque*, 121 USPQ 425; *In re Druey*, 138 USPQ 39. In all of these cases, the close structural similarity between two compounds

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differing by one or two methyl groups was itself sufficient show obviousness. See also MPEP 2144.09, second paragraph.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

There is no obvious double patenting with 09/623707, or 09/623726.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708-308-1235.



Mark L. Berch
Primary Examiner
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March 11, 2002